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July 27, 1993

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Dockets Management Branch (HFA-305) Food and Drug Administration Room 1-23 12420 Parklawn Drive Rockville, MD 20857

Subject: Intent to Amend Laser Products Performance Standard - Docket Number 93N-0044

This is in response to the Notice of Intent to amend the performance standard for laser products, 21CFR Part 1040. As a TEPRSSC member, I understand I will have an opportunity to comment on these proposals when submitted to the TEPRSSC committee. However, the following comments are submitted at this time in order to assist in the development of these proposed FDA modifications.

I fully support and encourage harmonizing the FDA laser standard with appropriate IEC standards. International standards harmonization provides benefits to manufacturers, test labs and product certifiers.

In II, "Amendments Under Consideration", paragraphs 12 and 13 suggest elimination of the signal words such as "caution" or "danger" in order to aline the FDA standard with the IEC standard. Eliminating the signal word should be reconsidered. U.S. consumers are accustomed to the type of markings that include a signal word. The standard three-part marking specified in most U.S. product safety standards, which are ANSI approved, requires the use of a signal word. The use of a signal words resulted from consensus agreements between consumer and legal interests in the United States a number of years ago.

DCY

I would be happy to discuss this issue, prior to or at the next TEPRSSC meeting. If you have any questions or would like further clarification, please do not hesitate to contact me.

Sincerely,

JOHN DRENGENBERG
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Vice President
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